REMARKS

This paper is filed in response to the Office Action issued December 14, 2007. Claims 1 and 4-22 had been presented. The Office Action rejected claims 1 and 4-22 for the reasons detailed below. Claims 15-16 have been cancelled, and claims 2-3 and 23-24 were cancelled in a previous response. Claims 1 and 13 have been amended. Claims 1, 4-14, and 17-22 remain pending.

Rejections under 35 U.S.C. § 102(b)

Claims 1, 4-10, and 14-19 were rejected under 35 U.S.C. § 102(b) as allegedly unpatentable over U.S. Patent No. 5,733,294 to Forber et al. (herein "Forber"). Applicants have amended these claims and respectfully request reconsideration.

Amended claim 1 recites a patent foramen ovale (PFO) closure device for providing compressive force to septum primum and septum secundum including a central body, a first and second end cap, and a first and second wire extending from the first end cap to the second end cap. The first wire and the second wire define first and second loops on one side of the PFO and third and fourth loops on the other side of the PFO. Each of the first and second loops extend from the central body to the first end cap. Each of the third and fourth loops extend from the central body to the second end cap. Each of the first and second loops define a first plane substantially parallel to septum primum and septum secundum, and the first and second loops cooperate with the central body to apply a force, perpendicular to the first plane, to overlapping layers of septum primum and septum secundum. Each of the third and fourth loops define a second plane substantially parallel to septum primum and septum secundum, and the third and fourth loops cooperate with the central body to apply a force, perpendicular to the second plane, to overlapping layers of septum primum and septum secundum.

Forber does not teach or suggest the recited combination of amended claim 1.

Thus, applicants respectfully traverse these rejections as Forber does not teach or suggest all of the limitations of amended claim 1. Specifically, Forber lacks loops that

apply a force to overlapping layers of septum primum and septum secundum that is perpendicular to planes that are substantial parallel to the septum primum and septum secundum.

The Office Action points to Fig. 8 of Forber and states that Forber teaches loops that apply a force perpendicular to planes that are substantially parallel to the septum primum and septum secundum. See Office Action at pg. 3. However, neither Fig. 8 nor Forber in general teach or suggest applying a compressive force to overlapping layers of septum primum and septum secundum of a patent foramen ovale (PFO).

Forber discloses devices for cardiovascular occlusion. Forber describes a device that has a predetermined pattern of wires helically wound in a braided pattern. Forber states that the primary use of the device is in embolotherapy to occlude blood vessels. See Forber at col. 3, lines 16-39. Forber also states that the device may be used to close a septal defect and illustrates, in Figs. 6-8, a device with two annular wire mesh disks. The device is shown in a septal defect such that one wire mesh disk is on either side of the septal defect. See Forber at col. 5, line 54-col. 6, line 2 and Fig. 8.

However, Forber does not teach or suggest the closure of a PFO. Although a PFO is one type of septal defect, septal defects also include simple holes in the septum of the heart (e.g., atrial septal defects and ventricular septal defects). Such a defect is illustrated in Fig. 8 of Forber. In contrast, a PFO is a unique type of defect that has overlapping layers of septal tissue, specifically, the septum primum and septum secundum. The defect shown in Fig. 8 lacks these overlapping layers of tissue.

Thus, applicants suggest that Forber does not describe a device with a central body for extending through a PFO and having loops that cooperate with said central body to provide a compressive force to overlapping layers of septum primum and septum secundum. Forber merely discloses a device for occluding a hole in the septal tissue of the heart by placing the device in the opening. For the reasons set forth below, applicant submits the device of Forber (shown in Fig. 8) is unacceptable for use in a PFO and lacks the structural limitations of amended claim 1.

The size and relative bulk of the center tubular portion between disks 130 and 132 and the braided nature of each disk prevent the disks from performing as required by claim 1. First, were the device to be placed in the pocket-like PFO defect, the bulky center tubular portion would prevent the septum primum and septum secundum from overlapping.

Furthermore, the overlapping layers of tissue would cause the center tubular portion to tilt at an angle within the defect, thereby assuming a non-perpendicular angle relative to the overlapping layers of tissue. Because the disks 130 and 132 are a braided mesh attached to the center tubular portion, the disks, when deployed, will tend to remain in a plane that is normal to the axis of the center tubular portion. Thus, as the center tubular portion tilts, disks 130 and 132 will also tilt relative to the overlapping layers of tissue. Thus, the plane of deployed disks 130 and 132 would no longer be parallel to the septum primum and septum secundum so as to provide a compressive force to these layers. Therefore, Forber lacks any teaching or suggestion of a device having structure adapted to provide compressive force to overlapping layers of tissue or the desirability of such structure.

In contrast, amended claim 1 clearly recites that the loops of the PFO closure device apply a force to overlapping layers of septum primum and septum secundum in a direction perpendicular to a plane substantially parallel to the septum primum and septum secundum. This compressive force acts to pinch the PFO defect closed. As described in the application, the configuration of elements recited in amended claim 1 may assume a skewed configuration relative to a line perpendicular to the septum primum and septum secundum. This flexibility between the central body, end caps, and wire loops enables the device to provide the compressive force to the overlapping layers of tissue. See Application at pg. 6, lines 4-26.

Therefore, because Forber does not teach or suggest all of the limitations of amended claim 1, claim 1 is patentable over Forber.

Claims 4-14 and 17-22 depend from claim 1. Thus, these claims include the combination recited in claim 1 and are patentable over Forber for at least the same reasons as claim 1.

Rejections under 35 U.S.C. § 103(a)

Claims 11, 13, and 20 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Forber in view of U.S. Patent No. 6,117,159 to Huebsch et al. (herein "Huebsch"). Claims 12 and 21-22 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Forber in view of Huebsch and in further view of U.S. Patent No. 6,355,052 to Neuss et al. (herein "Neuss"). Specifically, the Office Action states that Forber discloses the combination recited in independent claim 1, from which claims 11-13 and 20-22 depend, and relies on Huebsch and Neuss to provide the additional limitations set forth in the dependent claims.

As set forth in detail above, Forber does not teach or suggest all of the limitations of independent claim 1. Neither Huebsch nor Neuss provide these missing elements. Thus, claims 11-13 and 20-22 are patentable over the cited references for the same reasons given above for independent claim 1.

Claim Objections

Claims 15-16 were objected to because those claims depended from a cancelled claim. Claims 15-16 have been cancelled.

Conclusion

Applicants respectfully request an early and favorable reconsideration and issuance of this application as amended herein. The Examiner is encouraged to contact the undersigned to expedite prosecution of this application.

An authorization to charge the fees for the Information Disclosure Statement accompany this response. No other fees are believed to be due in connection with this

response. However, please charge any fees due in connection with this application or credit any overpayments to Deposit Acct. No. 08-0219.

Respectfully submitted,

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